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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,136	11/22/2006	David C. Bloom	36689.259	2666

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EXAMINER	
HIBBERT, CATHERINE S	

ART UNIT	PAPER NUMBER
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,136	BLOOM ET AL.	
	Examiner	Art Unit	
	CATHERINE HIBBERT	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-31,46-48,51,54 and 72-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-31,46-48 and 72-75* is/are rejected.

7)☒ Claim(s) *51 and 54* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/1/2007;8/17/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This is the First Office Action on the Merits of US Application 10/590,136, filed 17 August 2006, which is a National Stage entry of PCT/US05/05461, filed 17 February 2004, which claims priority to U.S. Provisional Application No. 60/545,375, filed 17 February 2004. Claims 8, 32-45, 49-50, 52-53 and 55-71 are cancelled. Claims 1-7, 9-31, 46-48, 51, 54 and 72-75 are pending and under examination.

Election/Restrictions

Applicant's election without traverse of Group I (Claims 1-7, 9-31, 46-48, 51, 54 and 72-75) in the reply filed on 23 April 2009 is acknowledged.

Claim Objections

Claims 51 and 54 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim *cannot depend from any other multiple dependent claim*. In the instant case, Claims 51 and 54 are multiple dependent claims that depend from the multiple dependent Claim 46. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claim 11 is objected to because of the following informalities: Claim 11 contains a typographical error in line 1 in the term "s aid". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 9-31, 46-48 and 72-75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "isolated" in parts (a), (b) and (c) in Claims 1 and 72-73 is an unclear term in the context of the “isolated polynucleotide” comprising the parts (a), (b) and (c) and which renders the claim indefinite. The term "isolated" is not defined by the claim, the specification does not provide a standard for ascertaining the meaning of the term in the context of the claim language. For example, it is unclear what is required of the sequences in parts (a), (b) and (c) to meet the limitation of “isolated” as the sequences are already contained in an “isolated” polynucleotide and therefore one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claims 2-7, 9-31, 46-48 and 74-75 are indefinite insofar as they depend from Claims 1 and 72-73.

Additionally, Claims 5-7, 13-16, 18-21, 23-26, 72-73 and 75 recite nucleotide sequence numbers that are not correlated to any specific SEQ ID NO in the specification or even correlated to any other specifically numbered sequence in the specification. For example, Claim 5 recites “from about nucleotide 118,975 to about nucleotide 120,471 of an HSV LAT 5 exon” but one of ordinary skill in the art cannot reasonably determine which sequences shown in the specification correlate to nucleotide 118,975 of an HSV LAT 5 exon and therefore the metes and bounds of Applicants invention cannot be determined.

Additionally, Claims 46-48 and 74, are indefinite insofar as they depend from Claim 73.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-7, 13-16, 18-21, 23-26, 46-48 and 72-75 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 5-7, 13-16, 18-21, 23-26, 72-73 and 75 recite nucleotide sequence numbers that are not specifically correlated to any specific SEQ ID NO in the specification or even correlated to any other specifically numbered sequence in the specification. For example, Claim 5 recites “from about nucleotide 118,975 to about nucleotide 120,471 of an HSV LAT 5 exon”. Sequences claimed in the product by nucleotide sequence number should be correlated to a specific SEQ ID NO in the specification and/or sequence listing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9-20, 22-25, 27-31, 46-48 and 72 are rejected under 35 U.S.C. 102(b) as being anticipated by Coffin and Latchman in "Eukaryotic Gene Expression Cassette and Uses Thereof" (WO 98/30707; published 16 July 1998; entire document; made of record in the IDS).

Claims read on a recombinant HSV vector (**Claims 46-48 and 72**) comprising an isolated polynucleotide that comprises:

(a) an HSV LAT enhancer element, consisting of a contiguous nucleotide sequence from about nucleotide 118,975 to about nucleotide 120,471 of an HSV LAT 5 exon (**Claims 1-7 and 72**);

(b) a first LAT insulator/boundary region, comprising a contiguous nucleotide sequence from nucleotide 8365 to nucleotide 9273 of HSV1, operably positioned upstream of said isolated LAT enhancer element (**Claims 17-20 and 72**);

(c) a second LAT insulatory/boundary region, comprising a contiguous nucleotide sequence from nucleotide 120,208 to nucleotide 120,940 of HSV1, operably positioned downstream of said isolated LAT enhancer element (**Claims 22-25 and 72**);

(d) a first promoter region operably positioned upstream of said LAT enhancer element, and downstream of said first LAT insulator/boundary region, wherein said

promoter region comprises an HSV LAP 1 promoter that consists of a sequence region of from nucleotide 117,938 to 118,843 of said HSV LAP1 promoter (**Claims 9-16**); and

(e) at least a first multiple cloning region operably positioned downstream of said first LAT insulator/boundary region and upstream of said LAT enhancer element (**Claim 27)** and wherein said first multiple cloning region further comprises a nucleic acid sequence that encodes a promoter or an enhancer sequence that is expressed in a mammalian host cell (**Claim 28**); and

(f) at least a second multiple cloning region operably positioned upstream of said second LAT insulator/boundary region and downstream of said LAT enhancer element (**Claim 29**) and that said second multiple cloning region further comprises at least a first nucleic acid sequence that encodes a therapeutic agent (**Claim 30**) and that the first therapeutic agent is selected from the group consisting of a peptide, a polypeptide, a ribozyme, a catalytic RNA molecule, an antisense oligonucleotide, and an antisense polynucleotide (**Claim 31**).

Coffin and Latchman teach recombinant HSV vectors (**e.g. abstract and page 8, lines 27-29**) comprising an isolated polynucleotide that comprises:

(a) an HSV LAT enhancer element, consisting of a contiguous nucleotide sequence from about nucleotide 118,975 to about nucleotide 120,471 of an HSV LAT 5 exon (**e.g. page 6, lines 1-5 and page 17, line 12-14**);

(b) a first LAT insulator/boundary region, consists of a contiguous nucleotide sequence from nucleotide 8365 to nucleotide 9273 of HSV1, operably positioned upstream of said isolated LAT enhancer element (**e.g. page 14, lines 10-26**);

(c) a second LAT insulatory/boundary region, consists of a contiguous nucleotide sequence from nucleotide 120,208 to nucleotide 120,940 of HSV1, operably positioned downstream of said isolated LAT enhancer element (**e.g. page 6, lines 1-5**);

(d) a first promoter region operably positioned upstream of said LAT enhancer element, and downstream of said first LAT insulator/boundary region, wherein said promoter region consists of an HSV LAP 1 promoter that consists of a sequence region of from nucleotide 117,938 to 118,843 of said HSV LAP1 promoter **(page 4, lines 15-16)**; and

(e) at least a first multiple cloning region operably positioned downstream of said first LAT insulator/boundary region and upstream of said LAT enhancer element (**page 6, lines 11-14, 29-37**) and wherein said first multiple cloning region further comprises a nucleic acid sequence that encodes a promoter or an enhancer sequence that is expressed in a mammalian host cell (e.g. **page 6, lines 11-14, 29-37**); and

(f) at least a second multiple cloning region operably positioned upstream of said second LAT insulator/boundary region and downstream of said LAT enhancer element (**e.g. page 16, lines 1-14**) and that said second multiple cloning region further comprises at least a first nucleic acid sequence that encodes a therapeutic agent (**page 7, lines 36-37**) and that the first therapeutic agent is a polypeptide of therapeutic use (**page 7, lines 36-37**).

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE HIBBERT whose telephone number is (571)270-3053. The examiner can normally be reached on M-F 8AM-5PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catherine S. Hibbert
Examiner/Au1636

/ Christopher S. F. Low /
Supervisory Patent Examiner, Art Unit 1636